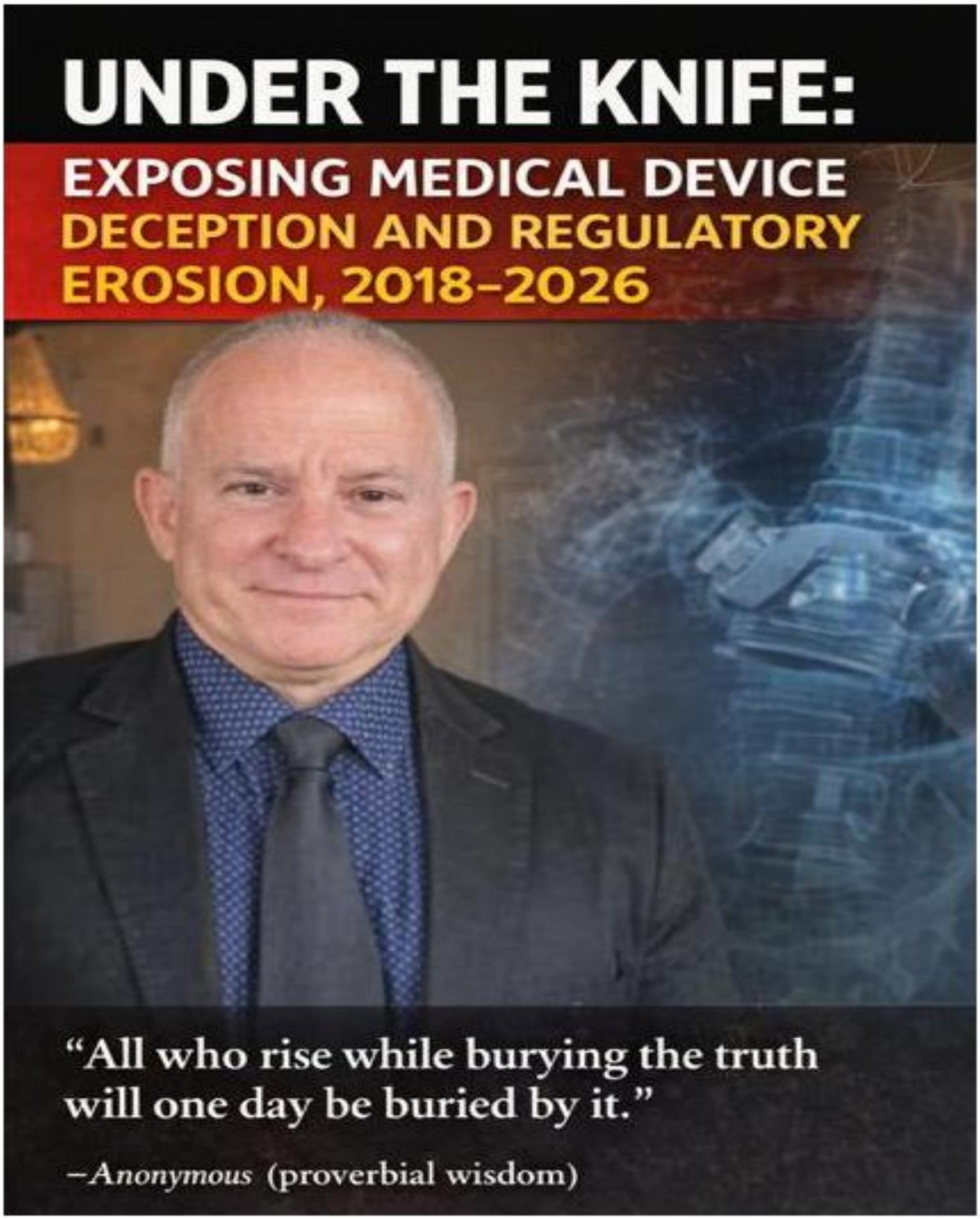

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Combined Medical Device ADVISORY And FDA Regulatory Framework Analysis

Structural Accreditation Fraud, Federal Contract Misrepresentation, and the Collapse of Medical Device Oversight (2018–2026)

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Section I — Press Advisory: Medical Device Recipients

PUBLIC ADVISORY — DIRECTED TO: Medical device recipients, healthcare providers, hospital systems, surgical centers, implant registries, device manufacturers, regulatory authorities, and all parties with standing in the conformity assessment chain governing medical device safety in the United States and internationally.

Between 2018 and the present date, medical devices — including but not limited to heart valves, hip implants, knee implants, surgical instruments, implantable cardiac devices, spinal fusion hardware, vascular stents, pacemaker components, life-support apparatus, and associated life-critical components — may have been manufactured, certified, and approved under an accreditation environment that has since been documented as **FRAUDULENT**. The compromise does not originate at the device level. It originates at the apex of the accreditation architecture itself.

The American National Accreditation Board (ANAB) falsely identified itself as an "***underwriter***" for the International Accreditation Forum (IAF Incorporated in Delaware) in **U.S. Department of State Contract No. 19AQMM18R0131**, awarded in 2018. No such role — "***underwriter***" — exists within the governance structures of the IAF or the International Laboratory Accreditation Cooperation (ILAC-Australia). No IAF bylaw, resolution, policy document, or governance framework authorizes, defines, or recognizes an "***underwriter***" function. This misrepresentation was not confined to the

federal contract; it was also published on a private laboratory website and disseminated in a technical journal, compounding the scope and visibility of the false claim. IAF & ILAC merged in January 2026 to GLOBAC- Global Accreditation Cooperation.

A second federal contract, **Contract No. 15F06725C0000139** (2025), further documents the continuation of ANAB's involvement in federal accreditation activities during the period in question. The existence of this **second contract** establishes that the federal government's reliance on ANAB's accreditation authority persisted through **2025** and into **2026** extending the window of exposure well beyond the initial **2018** misrepresentation.

It is imperative that all parties understand the following principle: *devices produced in an environment where the accreditation chain contains false information are affected by that environment, even if those devices function properly in clinical use. The defect at issue is not geometric, mechanical, or performance-related. The defect resides in the integrity of the oversight system that approved every step of manufacturing, validation, certification, and market clearance. A device may perform to specification. The system that certified it to specification is the system that has been* ***compromised****.*

The oversight environment is **COMPROMISED**. Between 2018 and 2026, medical devices may have been manufactured under accreditation conditions now in question, including but not limited to:

- **ISO 13485** certifications issued by ANAB-accredited certification bodies (**registrars**);
- **MedAccred** special-process approvals governing critical manufacturing operations such as heat treating, welding, chemical processing, coatings, and non-destructive testing;
- Supply-chain validations performed under accreditation frameworks reliant upon ANAB's authority;

- Quality-system oversight, surveillance audits, and recertification activities tied directly or indirectly to ANAB's accreditation status.

The structural collapse flows downward through the accreditation hierarchy. The Performance Review Institute (PRI) sits under ANAB's accreditation umbrella. **MedAccred** — the medical device special-process accreditation program — sits under PRI. The National Aerospace and Defense Contractors Accreditation Program (NADCAP) likewise sits under PRI. When the top of the accreditation chain is compromised by documented misrepresentation in a federal contract, everything beneath it becomes structurally contaminated. The integrity of subordinate programs cannot exceed the integrity of the authority from which they derive their accreditation status.

A waiver from the U.S. Food and Drug Administration cannot undo fraudulent oversight conditions. No administrative action, regulatory discretion, or enforcement forbearance can retroactively validate approvals, certifications, or market clearances issued under an accreditation environment whose foundational authority has been documented as **fraudulent.** The conditions under which devices were approved are historical facts. They cannot be revised by subsequent administrative action.

Section II — FDA Regulatory Framework: Applicable Standards and Legal Requirements

The following subsections identify and analyze the federal regulations directly implicated by a compromised accreditation environment. For each regulation, this analysis provides: (**1**) the full regulatory title and Code of Federal Regulations citation; (**2**) a plain-language explanation of the regulation's requirements; and (**3**) a statement explaining how a compromised accreditation environment violates, undermines, or renders structurally invalid the protections established by that regulation.

Subsection II-A: 21 CFR Part 820 — Quality System Regulation (QSR)

21 CFR Part 820 establishes the current Good Manufacturing Practice (cGMP) requirements for medical devices sold in the United States. This regulation governs the methods, facilities, and controls used for the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished medical devices intended for human use. Part 820 is the cornerstone of the FDA's regulatory architecture for ensuring that medical devices are safe, effective, and manufactured under controlled, documented, and reproducible conditions.

Part 820 requires each manufacturer to establish and maintain a quality system that is appropriate to the specific medical device(s) it designs or manufactures. The quality system must encompass management responsibility, design controls, document controls, purchasing controls, production and process controls, corrective and preventive action (CAPA), and records management, among other subsystems. Compliance with **Part 820 is not optional;** it is a condition of lawful manufacture and distribution of medical devices in the United States.

Impact of Compromised Accreditation: ISO 13485 is the internationally recognized quality management system standard harmonized with **21 CFR Part 820**. Manufacturers demonstrate compliance with Part 820 in substantial part through certification to ISO 13485, which is issued by certification bodies (**registrars**) that are themselves accredited by **accreditation bodies** — in the United States, primarily by **ANAB**. When the accreditation body certifying compliance with ISO 13485 has itself committed a documented **FRAUD** in a federal contract **No.19AQMM18R0131**— falsely claiming a governance role ("***underwriter***") that does not exist — the entire quality system certification is rendered structurally **INVALID**. The certification may bear a valid date and a valid certificate number, but the authority underlying it is compromised. The quality system regulation requires a quality system built on truthful, verifiable, and legitimate foundations. A certification issued under **fraudulen**t accreditation authority does not satisfy that requirement.

Subsection II-B: 21 CFR §820.10 — Requirements (Design Controls Scope)

21 CFR §820.10 sets forth the applicability requirements for the Quality System Regulation. This section establishes that each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of Part 820. Section 820.10 links directly to the design control requirements set forth in §820.30 and establishes the foundational expectation that manufacturers must demonstrate that their quality systems conform to recognized standards.

Impact of Compromised Accreditation: When the recognized standard — **ISO 13485** — is certified by an accreditation body operating under **fraudulent authority**, the manufacturer's compliance demonstration under **§820.10** is fundamentally undermined. The chain of conformity is broken at its origin. Section 820.10 requires an "appropriate" quality system. Appropriateness cannot be demonstrated through a certification whose accreditation foundation is **fraudulent.** The manufacturer may have implemented every required procedure, conducted every required review, and documented every required output — but the external validation of that system, through ISO 13485 certification under ANAB accreditation, carries the structural deficiency of the accreditation body's misrepresentation. The chain of conformity does not begin at the manufacturer's facility. It begins at the accreditation body. When that origin point is compromised, the entire chain is compromised.

Subsection II-C: 21 CFR §820.180 — General Requirements for Records

21 CFR §820.180 requires that all records required by Part 820 shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of the FDA designated to perform inspections. All records required under Part 820 must be legible, readily identifiable, and retrievable. Records must be complete, accurate, truthful, and unaltered. The integrity of the documentary record is not merely an administrative convenience; it is a regulatory requirement with direct implications for device safety and public health.

Impact of Compromised Accreditation: **Fraudulent** accreditation documentation embedded in the **quality system constitutes a violation** of **§820.180**. The records supporting the manufacturer's conformity assessment — including the ISO 13485 certificate, the accreditation mark, and the identity of the accrediting body — are founded upon a misrepresentation by the accrediting body itself. The manufacturer's quality system records incorporate, by reference and by reliance, the accreditation body's representations regarding its own authority and standing. When those representations are false — as documented in **Contract No. 19AQMM18R0131** — the records required under §820.180 are *structurally tainted*. The records may be legible and retrievable, but they are not truthful in their foundational premise. A quality system record that relies upon a **fraudulent** accreditation certificate is not a complete and accurate record within the meaning of §820.180.

Subsection II-D: 21 CFR §820.70 — Production and Process Controls

21 CFR §820.70 requires that all production processes shall be developed, conducted, controlled, and monitored to ensure that a device conforms to its specifications. Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. This section governs the critical manufacturing operations — heat treating, sterilization, coating, welding, chemical processing, and assembly — upon which device safety depends.

Impact of Compromised Accreditation: When the accreditation body that certified the quality system governing those production processes has been documented as operating under ***fraudulent authority***, the process validation required by **§820.70** is structurally compromised. This does not necessarily mean that any individual production process failed to produce a conforming device. The compromise is architectural, not necessarily operational. The oversight system that validated, monitored, and certified those production processes derived its authority from an accreditation body that misrepresented its own standing in a federal contract. Process validation under §820.70 requires not only that the process produce conforming results, but that the quality

system overseeing the process be itself valid. When the accreditation foundation is **fraudulent**, the process validation is structurally deficient — the oversight architecture that certified the process was itself invalid.

Subsection II-E: ISO 13485 — Medical Devices Quality Management Systems

ISO 13485 is the internationally recognized standard for quality management systems specific to the medical device industry. Published by the International Organization for Standardization (ISO), it specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. ISO 13485 is harmonized with **21 CFR Part 820** and is used by manufacturers worldwide to demonstrate compliance with regulatory requirements in the United States, the European Union, Canada, Japan, and other regulated markets.

Certification to ISO 13485 is issued by certification bodies (**registrars**) that are themselves accredited by accreditation bodies. In the United States, the primary accreditation body for ISO 13485 certification bodies is **ANAB**. The accreditation body's role is to ensure that the certification body is competent, impartial, and operating in accordance with the applicable international standards for conformity assessment (including ISO/IEC 17021-1). The accreditation body is the apex of the conformity assessment pyramid.

Impact of Compromised Accreditation: When ANAB's authority is documented as **fraudulent** — through its false claim of "*underwriter*" status for the IAF in **U.S. Department of State Contract No. 19AQMM18R0131** — every ISO 13485 certificate issued under ANAB accreditation during the affected period (2018–Present) is structurally compromised. The certificate may reflect a genuine audit, a competent certification body, and a compliant manufacturer — but the accreditation authority validating the certification body's competence and standing is the authority that committed the misrepresentation. The structural deficiency propagates downward: from *ANAB to the certification body, from the certification body to the manufacturer's ISO*

13485 certificate, and from the certificate to every device manufactured under its scope. This is not a theoretical concern. It is a documented condition with a specific contract number, a specific false claim, and a specific period of exposure.

Subsection II-F: 21 CFR Part 803 — Medical Device Reporting (MDR)

21 CFR Part 803 establishes the requirements for medical device reporting (MDR). This regulation requires manufacturers, importers, and device user facilities to report certain device-related adverse events and product problems to the FDA. The purpose of Part 803 is to ensure that the FDA receives timely information about significant device-related problems so that it can take appropriate corrective action to protect the public health.

Specifically, **21 CFR §803.50** requires manufacturers to report to the FDA when they receive or otherwise become aware of information that reasonably suggests that a device they market: (a) may have caused or contributed to a death or serious injury; or (b) has malfunctioned and such device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Impact of Compromised Accreditation: A compromised accreditation environment — one in which the foundational certification authority has been documented as **fraudulent** — constitutes a reportable condition under **Part 803**. The rationale is as follows: when the accreditation body that certified the quality systems governing medical device manufacture has committed a documented misrepresentation regarding its own authority, that misrepresentation represents a systemic condition that could affect the safety and effectiveness of ***every device manufactured*** under that accreditation umbrella. The malfunction, in this context, is not mechanical — it is institutional. The system designed to ensure device safety has itself malfunctioned at its highest level. Part 803 reporting obligations are triggered not only by individual device failures but by conditions that could contribute to device-related adverse events. A structurally compromised accreditation environment is precisely such a condition.

Subsection II-G: 21 CFR Part 806 — Medical Devices; Reports of Corrections and Removals

21 CFR Part 806 requires manufacturers and importers to report to the FDA any correction or removal of a medical device if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) caused by the device. A "correction" means any repair, modification, adjustment, relabeling, destruction, or inspection of a device without its physical removal from its point of use. A "removal" means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

Impact of Compromised Accreditation: If devices were manufactured under a structurally compromised accreditation environment, the determination of whether corrections or removals are necessary must account for the systemic nature of the oversight failure — not merely the performance characteristics of individual devices. The scope of **Part 806** extends to violations of the FD&C Act, which includes the requirement that devices be manufactured in accordance with current Good Manufacturing Practice as set forth in **21 CFR Part 820**. When Part 820 compliance is predicated upon ISO 13485 certification issued under **fraudulent** accreditation authority, a violation of the FD&C Act may exist independent of any physical defect in any individual device. The correction-and-removal analysis under Part 806 must therefore consider the accreditation environment as a factor in determining the scope and necessity of corrective action.

Subsection II-H: 21 CFR Part 821 — Medical Device Tracking Requirements

21 CFR Part 821 establishes tracking requirements for certain categories of medical devices. These categories include: (**a**) devices whose failure would be reasonably likely to have serious, adverse health consequences; (**b**) devices that are permanently implantable; and (**c**) devices that are life-sustaining or life-supporting and that are used outside a device user facility. The tracking requirements of Part 821 exist precisely because these devices carry the highest risk to patients and because the consequences

of device failure — or of systemic oversight failure affecting such devices — are the most severe.

Impact of Compromised Accreditation: When the accreditation environment governing the manufacture, certification, and regulatory approval of devices subject to **Part 821** tracking requirements has been compromised, the tracking requirements become even more critical. Tracking is the mechanism by which affected devices can be identified, located, and assessed in the field. The universe of potentially affected devices — *heart valves, pacemaker components, implantable cardiac defibrillators, hip and knee implants, vascular grafts, life-support equipment* — manufactured under ANAB-accredited quality systems between 2018 and Present can only be identified and evaluated through the tracking systems mandated by Part 821. The tracking requirements are not merely administrative; they are the operational infrastructure for responding to exactly this type of systemic oversight failure.

Section III — The December 2018 ANSI Takeover of ANAB: Structural and Legal Significance

On December 4, 2018, the American National Standards Institute (ANSI) announced its agreement to acquire full ownership interests in the ANSI-ASQ National Accreditation Board, LLC (ANAB) from the American Society for Quality (ASQ). The transaction closed on December 28, 2018. Upon completion of the acquisition, ANAB was renamed the "ANSI National Accreditation Board" and became a wholly owned subsidiary of ANSI. The joint-ownership structure that had existed since 2005 — under which ANAB was co-owned by ANSI and ASQ — was dissolved. Full control was consolidated under ANSI alone.

The legal and structural significance of this acquisition is substantial and must be understood in the context of the broader accreditation fraud documented in this analysis:

1. Consolidation of Authority. Prior to December 2018, ANAB was jointly governed by two entities — ANSI and ASQ — with separate institutional interests, governance structures, and accountability mechanisms. The December 2018 acquisition eliminated the dual-ownership structure and placed ANAB under the exclusive control of ANSI. This consolidation means that ANSI — the entity that writes, administers, and promulgates American national standards — now also owns and controls the entity that accredits the conformity assessment bodies responsible for certifying compliance with those standards. ***The standards-maker became the accreditation-gatekeeper***. This represents a structural conflict of interest of the **first order**: the entity that defines the requirements also controls the entity that determines who is competent to certify compliance with those requirements.

2. Temporal Coincidence with Federal Contract Fraud. The ANSI takeover of ANAB was consummated in December 2018 — the same year that **U.S. Department of State Contract No. 19AQMM18R0131** was awarded. This is the very contract in which ANAB falsely claimed "***underwriter***" status for the International Accreditation Forum (IAF). The false claim and the ownership consolidation occurred within the same calendar year. Whether this temporal coincidence reflects coordination, institutional negligence, or mere coincidence is a question that has not been addressed by any regulatory authority, congressional body, or court of law. The question itself, however, is one of profound structural significance.

3. Elimination of Independent Oversight. Under the pre-2018 joint-ownership structure, ASQ's participation in ANAB governance provided at least a nominal check on ANSI's influence over the accreditation process. The elimination of ASQ from the ownership structure removed that check. From December 28, 2018 forward, ANAB's operations, governance, board composition, and strategic direction have been determined exclusively by ANSI. Any misrepresentation committed by ANAB after that date is a misrepresentation committed by a wholly owned subsidiary of the national standards body of the United States.

4. Unresolved Structural Failure. The consolidation of standards-making authority and accreditation authority under a single corporate parent has not been subject to meaningful regulatory review, antitrust analysis, or public accountability proceeding. The structural conflict of interest created by this consolidation — and the temporal coincidence of the consolidation with documented federal contract fraud — represents a failure of institutional oversight that has persisted from 2018 to the present date.

Section IV — The FDA as Both Member and Customer of ANSI-ANAB

The U.S. Food and Drug Administration (FDA) occupies a dual role with respect to ANSI and ANAB that is directly relevant to the accreditation fraud documented in this analysis. This dual role creates obligations, conflicts, and questions of institutional accountability that must be addressed. **Systemic Certification Breakdown: FAA & FDA Standards Compromised by ANAB's Misrepresentation from 2018–2026** https://www.prlog.org/13135381-systemic-certification-breakdown-faa-fda-standards-compromised-by-anabs-misrepresentation-from-20182026.html

1. **FDA as Governance Participant.** The FDA sits as a member on the ANSI-ANAB board and participates in governance, committee work, standards development, and accreditation policy formulation. The FDA is not a passive observer of the ANSI-ANAB institutional framework; it is an active participant. FDA personnel serve on ANSI committees, contribute to the development of accreditation policies, and participate in the governance decisions that shape the conformity assessment landscape in the United States. The FDA's institutional presence within the ANSI-ANAB structure means that the agency is positioned — organizationally, informationally, and structurally — to be aware of the activities, representations, and governance conduct of ANAB. **ANSI**

National Accreditation Board (ANAB) Accredits Auditing Operation Services to Certify Foreign Food Supplies under U.S. FDA-FSMA Program
https://www.prnewswire.com/news-releases/ansi-national-accreditation-board-anab-accredits-auditing-operation-services-to-certify-foreign-food-supplies-under-us-fda-fsma-program-301269988.html

2. FDA as Customer and Reliant Party. The FDA is also a paying customer of ANAB's accreditation services. The FDA relies on ANAB-accredited certification bodies to verify that medical device manufacturers comply with ISO 13485 and, by extension, with **21 CFR Part 820**. The FDA's regulatory enforcement framework depends, in substantial part, on the assumption that ANAB-accredited certification bodies are competent, impartial, and operating under legitimate accreditation authority. The FDA does not independently audit every medical device manufacturer in the world; it relies on the conformity assessment infrastructure — an infrastructure that ANAB sits atop — to perform that function.

The legal and ethical implications of this dual role are as follows:

The FDA authored, promulgated, and enforces the very regulations — **21 CFR Parts 820, 803, 806, and 821** — that prohibit falsification, misrepresentation, and **fraudulent** documentation in the medical device quality system. These regulations do not contain exemptions for accreditation bodies, standards organizations, or government agencies. They apply to the quality system environment as a whole. From 2018 to Present, those regulations were violated at the apex of the certification chain — by the accreditation body itself (ANAB), under **Contract No. 19AQMM18R0131**.

The FDA, as both a board member of and a customer dependent upon the ANSI-ANAB institutional structure, was positioned to know — or, in the exercise of reasonable diligence, should have known — that the accreditation body it relied upon ***had committed a material misrepresentation****(****FRAUD****)in a federal contract. The FDA's regulatory authority is predicated upon the integrity of the systems it oversees. When the accreditation body at the top of that system commits a documented fraud, the FDA's*

continued reliance on that accreditation body — without investigation, disclosure, or corrective action — raises fundamental questions of regulatory accountability.

The FDA wrote the rules. The FDA enforces the rules. The FDA participates in the governance of the entity that violated the rules. The FDA cannot exempt itself from the regulatory framework it created, nor can it disclaim responsibility for the integrity of the accreditation infrastructure upon which its own enforcement regime depends.

Section V — Two Federal Contracts: The Documentary Record

The evidentiary foundation of this analysis rests upon two federal contracts. These contracts are government records. They are permanent. They are subject to the Federal Acquisition Regulation, the False Claims Act, and the documentary-integrity requirements applicable to all federal procurement instruments. Their contents speak for themselves.

Contract 1: U.S. Department of State Contract No. 19AQMM18R0131 (2018)

This is the contract in which ANAB made the following representation: *"ANAB is an **underwriter** for the International Accreditation Forum (IAF)."* No such role exists. No IAF governance document — including the IAF Bylaws, the IAF Articles of Association, the IAF Memorandum of Understanding, or any IAF General Assembly resolution — authorizes, defines, recognizes, or contemplates an "underwriter" function. The term "underwriter" has no meaning within the IAF or ILAC governance frameworks. ANAB's insertion of this false claim into a federal contract constitutes a misrepresentation in a permanent government record. This false claim was not confined to the contract itself; it was also published on a private laboratory website and disseminated through a technical publication, extending the scope of the misrepresentation beyond the federal procurement context and into the broader conformity assessment community.

Reference **GUBERMAN-ANOMALY-DISCOVERY** https://guberman-quality.com/wp content/uploads/2026/03/GUBERMAN-ANOMALY-FEBRUARY-2026.docx.pdf

Contract 2: Federal Contract No. 15F06725C0000139 (2025) DOJ

This contract documents the continuation of ANAB's involvement in federal accreditation services. Its existence establishes a critical fact: federal reliance on ANAB's accreditation authority did not cease after the 2018 misrepresentation. It continued. Through 2019, 2020, 2021, 2022, 2023, 2024, 2025, and into 2026, the federal government continued to rely upon ANAB as a legitimate accreditation authority. **Contract No. 15F06725C0000139** is the documentary proof of that continued reliance. Every year of continued reliance is a year of compounded exposure — exposure for device manufacturers, for certification bodies, for healthcare providers, for patients, and for the federal government itself. The DOJ is not just a member on ANSI-ANAB board but it is also a customer.

Government contracts do not disappear. They are archived, indexed, and retrievable. The fraud documented in **Contract No. 19AQMM18R0131** is a permanent record of the United States government. The continuation of federal reliance on ANAB, as documented in **Contract No. 15F06725C0000139**, extends the period of exposure, the scope of liability, and the universe of affected parties. Together, these two contracts define both the origin and the duration of the accreditation fraud that is the subject of this analysis.

Section VI — The Compounding Effect: From Accreditation Fraud to Device-Level Risk

The manufacturing of medical devices is a sequential, cumulative process. Each operation depends upon the validity of the operations and certifications that precede it. This sequential dependency is not incidental; it is the defining structural characteristic of

regulated manufacturing. It is also the mechanism by which accreditation fraud at the top of the oversight chain propagates to the device level.

From 2018 to Present, every manufacturing step that relied upon ANAB-accredited quality system oversight — or upon **MRA/MLA**-equivalent international accreditation body oversight derived from the same multilateral recognition framework — was performed under an accreditation environment now documented as structurally compromised **FRAUDULENT**. These manufacturing steps include, but are not limited to:

- Heat treating of metallic components (titanium alloys, cobalt-chromium alloys, stainless steels);
- Chemical processing, including passivation, anodizing, and surface treatment;
- Coating operations, including plasma spray, hydroxyapatite coating, and antimicrobial surface treatments;
- Precision machining of implant geometries and critical tolerances;
- Forming operations, including forging, casting, and additive manufacturing;
- Assembly of multi-component devices, including cardiac devices, joint replacement systems, and spinal implant assemblies;
- Sterilization — ethylene oxide, gamma irradiation, electron beam, and steam sterilization;
- Final acceptance inspection, testing, and release.

In medical device manufacturing, **each** of these processes depends upon the validity of the certification that preceded it. The raw material was procured from a supplier whose quality system was certified under the same accreditation umbrella. The incoming inspection was performed under procedures validated by the same quality system. The process validation was conducted under the oversight of a certification body accredited by the same accreditation body. Each step in the manufacturing sequence incorporates, by reference and by reliance, the accreditation authority at the top of the chain.

When that foundational accreditation is **fraudulent**, every subsequent operation compounds the deficiency. A sterilized implant carries the structural deficiency of every preceding step — machining, coating, assembly, packaging — each of which was performed under the same compromised oversight architecture. A validated production line carries the deficiency because its validation was certified under a quality system accredited by a **fraudulent** authority. A certified clean room carries the deficiency because its certification was issued under the same accreditation umbrella.

The defect is not visible on the device. It does not appear in dimensional inspection. It is not detectable by non-destructive testing. It resides in the integrity of the system that approved every step — from raw material procurement to final release. Once the root accreditation is compromised, every downstream process inherits that compromise. The compounding is cumulative, irreversible, and structural. No final inspection, acceptance test, clinical trial, or regulatory waiver can reverse the conditions under which the device was originally approved. The conditions of approval are historical facts. They cannot be retroactively altered by administrative action.

Section VII — Conclusion and Declaratory Statement

This analysis documents, with specificity and evidentiary grounding, the following conclusions:

1. The accreditation environment governing medical device manufacturing in the United States — and, through mutual recognition agreements, internationally — has been documented as ***structurally compromised*** from 2018 to Present. The compromise originates in a false representation made by the American National Accreditation Board (ANAB) in **U.S. Department of State Contract No. 19AQMM18R0131**, in which ANAB falsely claimed to be an "***underwriter***" for the International Accreditation Forum (IAF) — a role that does not exist.

2. The regulatory framework governing medical device quality systems — **21 CFR Part 820** (including **§820.10**, **§820.70**, and **§820.180**), **ISO 13485**, **21 CFR Part 803**, **21 CFR Part 806**, and **21 CFR Part 821** — was authored, promulgated, and enforced by the U.S. Food and Drug Administration. These regulations ***prohibit*** falsification, misrepresentation, and **fraudulent** documentation in the quality system. Those prohibitions were violated at the apex of the accreditation chain.

3. The FDA occupies a dual role as both a governance participant (board member) and a paying customer of the ANSI-ANAB institutional structure. The FDA was positioned to know — or, in the exercise of reasonable diligence, should have known — that the accreditation body upon which its regulatory enforcement regime depends had committed a material misrepresentation in a federal contract. The FDA's continued reliance on ANAB, without investigation or corrective action, raises fundamental questions of regulatory accountability. **FDA Recognizes First Accreditation Body Under Accredited Third-Party Certification Program and Launches Voluntary Qualified Importer Program** https://www.khlaw.com/insights/fda-recognizes-first-accreditation-body-under-accredited-third-party-certification-program

4. Two federal contracts define the scope and duration of the documented fraud. **Contract No. 19AQMM18R0131** (2018) contains the false "underwriter" claim. **Contract No. 15F06725C0000139** (2025) documents the continuation of federal reliance on ANAB's accreditation authority through 2025 and into 2026. Together, these contracts establish an eight-year period of compounded exposure affecting every medical device manufactured under ANAB-accredited quality system oversight.

5. On **December 28, 2018**, ANSI completed its acquisition of full ownership of ANAB, consolidating standards-making authority and accreditation authority under a single corporate parent. This consolidation occurred in the same year as the federal contract in which the false "***underwriter***" claim was made. The structural conflict of interest created by this consolidation — and its temporal coincidence with documented fraud — has not been subject to regulatory review, antitrust scrutiny, or public accountability.

6. The compounding effect of accreditation fraud in a sequential manufacturing environment means that every device manufactured under the compromised accreditation umbrella — from raw material procurement through final release — carries the structural deficiency of the oversight system that approved it. This deficiency is cumulative, irreversible, and not remediable through final inspection, testing, or administrative waiver. **Two Federal Contracts, One Unresolved Fraud: 19AQMM18R0131 (2018) and 15F06725C0000139 (2025)**
https://www.prlog.org/13140143-two-federal-contracts-one-unresolved-fraud-19aqmm18r0131-2018-and-15f06725c0000139-2025.html

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"There is no waiver, no exception, and no administrative workaround that can erase the consequences of falsified accreditation."

"The world is rarely healed by institutions. It is healed by the one individual who sees the wound clearly enough — and cares deeply enough — to close it."
I have seen the wound, I have mapped the fracture, I am offering the repair.
2026- Daryl Guberman

"All who rise while burying the truth will one day be buried by it."
-Anonymous (proverbial wisdom)

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that the information in this document is true, accurate, and supported by corroborating evidence. This electronic signature is executed by DARYL GUBERMAN on **April19, 2026 at 11:26 PM** Electronic Signature:

Daryl Guberman

DARYL GUBERMAN